November 5, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re/ Application of Kenneth Iain Cumming and
Zebunnissa Ramtoola
Application No. 09/510,560 Examiner: J. Lundgren
Filed February 22, 2000 Art Unit 1639
Confirmation No. 3011

SOLID ORAL DOSAGE FORM CONTAINING AN ENHANCER

(Attorney Docket No. P24,375-A USA)

ELECTRONICALLY FILED

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

37 C.F.R. 1.132 DECLARATION OF JAMES SWARBRICK D.Sc., Ph.D.

I, James Swarbrick, D.Sc., Ph.D., declare as follows.

POSITION AND QUALIFICATIONS

1. I am presently a principal of PharmaceuTech, Inc., a consulting company located in Pinehurst, NC. I am expert on the formulation of active pharmaceuticals in various dosage forms and I have a thorough knowledge of the practical considerations that should be taken into account during the formation of dosage forms including tablet and capsule formulations. My Curriculum Vitae, which lists my past and present positions, duties, and publications, is attached hereto.

2. I have read and understood Irish Patent No. (11) 63119 to Bachynsky et al., and U.S. Patent No. 5,190,748 to Bachynsky et al. (collectively, "Bachynsky"), and Published PCT Application No. WO 97/05903 to Watts et al. ("Watts"), each of which have been cited in the pending Office Action.

PHARMACEUTICAL FORMULATIONS

3. It is generally known that a pharmaceutically active compound must be present in solution in the gastrointestinal tract (GIT) before it can pass through the epithelial cells lining the GIT wall (by any of a variety of mechanisms) and into the patient's bloodstream.

4. In the pharmaceutical industry, drug formulations are usually developed initially as liquid formulations as these forms are the simplest to manufacture and test. However, in the development of a particular active ingredient, there is a general desire in the industry to progress from liquid formulations to solids (e.g. powder, capsule, granulate, tablet, etc.).

5. The desire to progress to solid forms can be traced to a number of advantages common to solid formulations that cannot be readily obtained by using liquids. These advantages include the following:

- Greater stability of active compounds in the solid state.
- Longer shelf life of solids over liquid formulations.
- Solid forms more tamper-evident than liquids.
- Greater dosing accuracy in solid dosage forms.
- Lower manufacturing costs for solid dosage forms
- Lower shipping, packaging, and storage costs for solid forms.

6. Various different solid formulations exist including tablets, capsules, granulates, and powders. In the pharmaceutical industry, there is a general preference for tablets over capsules, and a preference for capsules over liquid formulations. Both tablets and capsules are preferred over liquid formulations as they each provide convenient unit

dosage forms, and tablets are preferred over capsules as they are easier and less expensive to manufacture.

TABLETTING CONSIDERATIONS

7. Although tablets are the drug formulation of choice, the formation of tablets requires the careful manipulation of a variety of different parameters. The typical procedure for forming a pharmaceutical tablet, described in broad terms, involves: (1) forming a compressible powder or granulate blend of the tablet components; and (2) compressing an amount of the powder or granulate blend in a tablet press to form a tablet. If desired, the tablet may then be coated with a coating to modify and/or delay the release of the tablet components from the tablet. Powder or granulate blends that are to be compressed into tablets may be formed by "dry" methods, such as by the dry blending of powders or granules of the tablet components, or by "wet" methods, such as by the forming of a paste, slurry, or solution of the tablet components which is then spray dried or granulated to form a free flowing powder or granulate.

8. One important factor in the formation of tablets is that the powder or granulate blends that are to be compressed into tablets are dry, preferably free-flowing, materials. If the material is not dry, or if it is a waxy or a paste material, it does not flow freely into the tablet press and is difficult to compact into tablet. Where such material can be compacted, it is difficult to form a tablet that is properly released from the tablet press and that has the requisite structural integrity.

9. In general, the dosage forms described in Bachynsky are capsules that are filled with the mixture of a drug and a two-component enhancer system. The only disclosure of non-capsule forms is on page 7, lines 15-19 where Bachynsky mentions the possibility of forming tablets and proposes absorbing a liquid formulation onto a carrier followed by compression to form a tablet.

10. All of the drug formulations disclosed in Bachynsky include the polyoxyethylene glycol lauryl ether Laureth-12. Laureth-12 has a melting point just above room

temperature and is a soft waxy compound at room temperature. Many of the formulations in Bachynsky also contain "Witepsol H15" which is typically used as a suppository base. Notably, even the oral formulations described in Bachynsky include Witepsol H15 (for example the compositions on page 14, lines 15-19). Witepsol H15 also has a melting point just above room temperature and is also a soft waxy compound at room temperature. In view of the materials Bachynsky teaches as suitable for two-component enhancer system, the absorption enhancers that Bachynsky discloses would be considered microemulsions, a term that is generally understood to refer to stable liquid systems of water, oil, and an amphiphile.

11. All of the oral formulations in Bachynsky contain a considerable amount of these low-melting waxy compounds (e.g., Laureth-12 and Witepsol H15). For example the compositions described in the table on page 14 of Bachynsky contain between 47% and 62% (weight percent) waxy compounds. As described above, these waxy compounds make it very difficult to compress the compositions into tablets because they are soft and sticky. In my opinion, it would not be practical, and therefore not commercially viable, to form tablets by simply compressing the compositions described in Bachynsky.

12. The proposal in Bachynsky to absorb a liquid formulation onto a carrier followed by compression to form a tablet (page 7, lines 15-19) is not actually a viable proposal for the compositions described in Bachynsky. Because the compositions all contain significant amounts of a soft, low-melting material (Laureth-12 and/or Witepsol H15), a very large amount of carrier (such as silica) would be required to provide a composition dry enough to be successfully pressed into tablets. The use of such large amounts of carrier material would result in either a tablet suitable for oral administration but too small to contain a unit dose, or a unit dose tablet too large to be orally administered.

13. Furthermore, despite the statements in Bachynsky, I am not aware of any actual use in the industry of a tablet preparation process in which a solution is absorbed onto a solid carrier which is then compressed to form a tablet.

14. Watts describes a drug delivery composition including a polar drug and a two-component "absorption promoter" which can be a mixture of a fatty acid or fatty acid salt having 6-16 carbon atoms, and a dispersing agent such as Labrasol (page 5, lines 10-16). In view of the materials Watts describes as suitable for the two-component absorption promoter, the absorption enhancers that Watts discloses would be considered microemulsions. Watts also mentions, in generalized terms, formulating the compositions as tablets or pellets (page 9, lines 14-17) using "known tablet constituents and methods." The compositions in Watts are "liquid or semi-solid" depending on the length of the fatty acid carbon chain (page 8, line 21-23), and those presented in the examples of Watts are all either liquids or pastes.

15. A composition of sodium insulin and capric acid, as described in Example 3 of Watts, has been produced in accordance with the teachings of Watts. The final composition, at room temperature, is a semi-solid mass of sodium insulin and capric acid in the form of a paste.

16. In order to form tablets from any of the compositions described in Watts, it would be necessary to alter such compositions substantially in order to form a compressible powder or granulate blend. Any suggestion to absorb the liquids of Watts onto a carrier material (such as proposed in Bachynsky) suffers from the same problems noted above with respect to Bachynsky, i.e., the need for significant quantities of carrier material. Therefore, despite the reference in Watts to "known tablet constituents and methods," I am not aware of tablet constituents or methods that could be used to make commercially viable, orally administrable tablets from the compositions described in Watts.

DELAYED RELEASE COATINGS

17. In some circumstances, it may be desirable to apply a coating to a tablet in order to isolate the tablet components from the stomach. Such coated tablets are commonly

referred to as delayed release or enteric tablets. Delayed release tablets may be desirable where the active component in the tablet can be degraded by acidic environments, or where any of the components of the tablet may be stomach irritants. In these situations, the coating serves to isolate the tablet components from the stomach environment to avoid the undesirable stomach irritation or loss of tablet efficacy.

18. A delayed release coating may be formed from material that is a solid at room temperature and that is melted, applied as a molten state, and which then cools to form the coating. Alternatively, the coating material may be applied as a solution or suspension which is then dried to form the coating. In either case, one of the steps in the coating process (the coating step in the first case, and the drying step in the second case) is performed at elevated temperatures. As a result, the components of the tablet must be chemically and structurally stable at these elevated temperatures. Accordingly, while a tablet may be formed containing a significant amount of a component having a melting point below 50°C, it would not be possible to apply a delayed release coating to such a tablet without substantial risk of losing tablet integrity due to the melting of one or more of the components.

19. I hereby declare that all statements made herein are of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application for which it is submitted and any patent issued thereon.

Dated November 5, 2007

JAMES SWARBRICK D.Sc., Ph.D.

JAMES SWARBRICK

Curriculum Vitae

PERSONAL INFORMATION:

Business Address:	PharmaceuTech, Inc., 180 Doral Drive, Pinehurst, NC 28374-8682 T: 910-255-3015; E-mail pharmaceutech@earthlink.net
Home Address:	180 Doral Drive, Pinehurst, NC 28374-8682 T: 910-255-3015; E-mail pharmaceutech@earthlink.net
Place of Birth:	London, England
Citizenship:	U.S.A. (naturalized May 23, 1974, Albany, NY)
Marital Status:	Married (Pamela Margaret)
Military Service:	Royal Air Force, Middle East Command, 1954-56

EDUCATION:

1960	B.Pharm. (Hons), London University
1961	Ph.C. Diploma, Royal Pharmaceutical Society of Great Britain
1964	Ph.D. in Pharmaceutics, Faculty of Medicine, London University
1972	D.Sc. in Surface and Physical Chemistry, London University

PROFESSIONAL BACKGROUND:

2000-present	President, PharmaceuTech, Inc.
1999-2006	Vice President for Scientific Affairs, AAI (Applied Analytical Industries, Inc.)
1993-1999	Vice President for Research & Development, AAI
1993-present	Adjunct Professor, School of Pharmacy, University of North Carolina at Chapel Hill
1981-1993	Professor and Chairman, Division of Pharmaceutics and Director of Graduate Studies, School of Pharmacy, University of North Carolina at Chapel Hill
1978-1981	Professor of Pharmacy and Chairman, Graduate Education and Research Council, School of Pharmacy, University of Southern California
1976-1978	Dean, The School of Pharmacy, University of London, England
1975-1976	Professor of Pharmaceutics, University of Sydney, Australia
1972-1975	Director of Product Development, Sterling-Winthrop Research Institute, (Sterling Drug, Inc.), Rensselaer, N.Y.
1970-1972	Assistant Dean for Research and Graduate Studies, School of Pharmacy, University of Connecticut
1969-1972	Professor and Chairman, Pharmaceutics Division, School of Pharmacy, University of Connecticut
1966-1969	Associate Professor, School of Pharmacy, University of Connecticut
1964-1966	Visiting Assistant Professor and then Associate Professor, School of Pharmacy, Purdue University
1960-1964	Research Assistant, Assistant Lecturer and then Lecturer, Pharmacy Department, Chelsea College, London University
1960-2004	Registered Pharmacist, U.K.

ADMINISTRATIVE AND UNIVERSITY ACTIVITIES AT UNC-CH:

1981-1993	Director of Graduate Studies, School of Pharmacy
1981-1993	Chairman, Graduate Education and Research Committee, School of Pharmacy
1981-1989	Member, Administrative Board, School of Pharmacy
1983-1984	Chairman, Ad Hoc Committee on Faculty Code, School of Pharmacy
1984-1985	Chairman, Hearing Subcommittee for Graduate Student Petitions, UNC-CH
1984-1985	Chairman, Ad Hoc Committee on Appointment, Reappointment, and Tenure Policy, School of Pharmacy
1984-1990	Member, Administrative Board, Graduate School, UNC-CH
1984-1990	Member, Program Review Subcommittee, Graduate School, UNC-CH
1985-1986	Member, University Search Committee for Vice Chancellor of Research and Dean of the Graduate School, UNC-CH
1985-1988	Chairman, Ad Hoc Committee on Pharm D-PhD program, School of Pharmacy
1987-1988	Member, University Blue Ribbon Committee, UNC-CH
1989-1990	Member, University Search Committee for Associate Provost and Dean of the Graduate School, UNC-CH
1990-1993	Member, Biomedical Research Grants Committee, UNC-CH
1991-1993	Member, Enrollment Management Committee, UNC-CH

NATIONAL AND INTERNATIONAL COMMITTEE APPOINTMENTS:

1969-1971	Member, Committee on Graduate Programs, AACP
1970-1974	Member, Committee on Public Relations, Academy of Pharmaceutical Sciences
1970	Member, Committee on Undergraduate Research Awards, AACP
1970-1975	Member, Committee on Specifications, National Formulary
1971-1975	Chairman, Joint United States Pharmacopeia-National Formulary Panel on Disintegration and Dissolution Testing
1975-1976	Member, Practice Training Committee, Pharmaceutical Society of NSW, Australia
1976	Member, Therapeutic Goods and Cosmetic Advisory Committee, Health Department of New South Wales, Australia
1976-1978	Member, Education Committee, Royal Pharmaceutical Society of Great Britain
1977-1978	Member, Working Party on Pre-Registration Training for Pharmacists, Royal Pharmaceutical Society of Great Britain
1977-1978	Co-founder and first Vice Chairman, Committee of Heads of Schools of Pharmacy in the United Kingdom.
1979	Ad-Hoc Member, NIH Study Section in Pharmacology
1979-1983	Member, Resolutions Committee, Academy of Pharmaceutical Sciences
1980-1982	Member, Ebert Prize Committee, Academy of Pharmaceutical Sciences
1980-1982	Member, Volwiler Award Review Panel, AACP
1982-1990	Member, Basic Pharmacology Advisory Committee, Pharmaceutical Manufacturers Association Foundation
1984-1985	Member, US Army MRDC Advisory Subcommittee on Medical Defense Against Chemical Agents
1984-1986	Member, Research Funding Committee, Academy of Pharmaceutical Sciences
1986	Chairman Elect, North Carolina Pharmaceutical Discussion Group
1986-present	Chairman, Pharmaceutics Advisory Committee, PhRMA Foundation
1986-present	Member, Scientific Advisory Committee, PhRMA Foundation
1996-present	Special Government Employee, FDA
1986-1989	Member, Advisory Committee, Industrial Pharmaceutical Institute, N.C. Department of Community Colleges.

NATIONAL AND INTERNATIONAL COMMITTEE APPOINTMENTS (continued):

1987	Chairman, North Carolina Pharmaceutical Discussion Group
1987-1988	Member, Membership Committee, Pharmaceutical Technology Section, American Association of Pharmaceutical Scientists (AAPS)
1989-1991	Chairman, Publications Committee, Pharmaceutics & Drug Delivery Section, AAPS
1989-1991	Member, Publications Committee, AAPS
1990-1996	Member, International Advisory Board, Shri B. V. Patel Pharmaceutical Education and Research Development Centre, Ahmedabad, India
1991	Member, Program Planning Committee, Pharmaceutics and Drug Delivery Section, AAPS
1991-1992	Member 1992 Arden House Planning Committee and Faculty
1992-1996	Member, Generic Drugs Advisory Committee, Food and Drug Administration (now Pharmaceutical Science Advisory Committee)
1994-1996	Chairman, Generic Drugs Advisory Committee, FDA (now Pharmaceutical Science Advisory Committee)
1996-1998	Member, Council of Chairs, Center for Drug Evaluation and Research, FDA

CONSULTANTSHIPS:

1965-1967	Rowell Laboratories, Baudette, Minnesota
1967-1972	Sterling-Winthrop Research Institute, Rensselaer, NY
1971	Astra Pharmaceutical Co., Sweden, Guest Scientist
1975-1976	Department of Health, Australian Government, Canberra
1975-1976	Sterling Pharmaceutical Pty. Ltd., Australia
1976-1985	Sterling-Winthrop Research and Development, U.K.
1977-1978	Science University of Malaysia, External Examiner
1977-1987	Fisons plc, Pharmaceutical Division, U.K.
1978	Organization of American States, Washington, DC
1979	Pan American Health Organization, WHO, Washington, DC
1979-1982	American Critical Care Laboratories, Chicago
1980	World Health Organization, Geneva
1981	Pan American Health Organization, Rio de Janeiro, Brazil
1981	University of El Fatah, Tripoli, Libya
1981-1982	National University of Singapore, External Examiner
1982-1985	Burroughs Wellcome Company, Research Triangle Park, NC
1987-1989	The Upjohn Company, Kalamazoo, MI
1989-1990	Becton Dickinson Research Center, Research Triangle Park, NC
1989-1991	Knowledgelink, Ltd, London, U.K.
1990-1992	Alcon Laboratories, Inc., Fort Worth, Texas
1991-1992	Intermatrix, London, U.K.
1991-1992	Adcock Ingrams, Johannesburg, South Africa
1992	Glaxo Inc, Research Triangle Park, NC
1992	Viaderm, Inc, (Member of Scientific Advisory Board) Research Triangle Park, NC
1992	General Nutrition Products, Inc., (Science Advisory Committee), Greenville, SC
1992	Smith & Nephew - Solopak, Chicago, IL
2000	Collabra Pharmaceuticals, San Francisco, CA
2000-2004	Endeavor Pharmaceuticals, Wilmington, NC
2000-2004	Genta Inc, Berkeley Heights, NJ
2001-present	Novacea, Inc., San Francisco, CA
2001-2003	Verion, Inc., Exton, PA
2002-present	Wilmington Pharmaceuticals LLC, (Member, Board of Advisors), Wilmington, NC
2003-2004	Synergia Pharma, Inc., South San Francisco, CA

EDITORIAL ACTIVITIES AND JOURNAL REVIEWER:

1964-present	Served as reviewer for numerous journals, including Journal of Pharmaceutical Sciences, Journal of Pharmacy and Pharmacology, Pharmaceutical Technology, Australian Journal of Pharmaceutical Sciences, Science, Journal of Investigative Dermatology, Biopharmaceutics and Drug Disposition, Life Sciences, and International Journal of Pharmaceutics. Also Environmental Protection Agency, Lea and Febiger, John Wiley & Sons and Marcel Dekker Inc.
1970-1973	Series Editor, "Current Concepts in the Pharmaceutical Sciences" (2 volumes. published)
1973-1979	Editorial Board, "Journal of Biopharmaceutics and Pharmacokinetics"
1974-1981	Editorial Board, "Drug Development and Industrial Pharmacy"
1975-present	Series Editor, "Drugs and the Pharmaceutical Sciences" (136 volumes published to date)
1978-1980	Editorial Board, "Pharmaceutical Technology International"
1978-1985	Editorial Board, "Asian Journal of Pharmaceutical Sciences"
1979-present	Editorial Board, "Biopharmaceutics and Drug Disposition"
1980-present	Editorial Board, "Pharmaceutical Technology"
1985-2005	Co-editor, "Encyclopedia of Pharmaceutical Technology" (1^{st} and 2^{nd} editions)
2005-present	Editor, "Encyclopedia of Pharmaceutical Technology" (3^{nd} edition)

SOCIETY MEMBERSHIPS:

Honorary	Rho Chi Pharmacy Honor Society
	Kappa Psi
Scientific &	Academy of Pharmaceutical Sciences (Elected Fellow)
Professional	Royal Society of Chemistry (Elected Fellow)
	Royal Pharmaceutical Society of Great Britain (Elected Fellow)
	American Association of Pharmaceutical Scientists (Elected Fellow)
	American Association of Colleges of Pharmacy

HONORS AND AWARDS:

1966; 1972	Awarded Lederle Pharmacy Faculty Research Award
1967	Awarded Mead Johnson Research Award
1970	Elected Fellow of the Royal Institute of Chemistry (now Royal Society of Chemistry)
1972	National Science Foundation-American Association of Colleges of Pharmacy Visiting Scientist, University of Florida and Florida A&M
1973	Elected Fellow of the Academy of Pharmaceutical Sciences
1978	Elected Fellow of the Royal Pharmaceutical Society of Great Britain
1978	Elected Life Member of Body Corporate, University of London School of Pharmacy
1988	Awarded Kenan Research Study Leave, University of North Carolina
1988	Visiting Professor, Brighton Polytechnic, U.K.
1991-1992	Visiting Professor, Shanghai Medical University, Peoples Republic of China
also	Listed in "American Men and Women of Science," "Men of Achievement," 4th edition, Debrett's "People of Today," and "Who's Who."

MAJOR RESEARCH AND CORPORATE INTERESTS:

Drug delivery systems - Drug availability and control of drug release from liquid, solid, and semisolid pharmaceutical dosage forms - Dosage form optimization through formulation - In vitro dissolution in relation to in vivo availability - Drug permeation through membranes, particularly human skin - Phase equilibria in multicomponent systems - Optimization of R&D organizations - Effectiveness of preformulation studies - SUPAC issues.

RESEARCH PROPOSALS FUNDED:

Funding Source	Title of Proposal	Period of support	Amount awarded
Purdue Res Fnd[n]	Ross-Ade Research Award	4/65-3/66	$2,000
National Sci Fnd[n]	Instructional Scientific Equipment Pgm	5/67-4/68	$20,800
UConn Res Fnd[n]	Drug Action on Model Membranes:	12/66-11/67	$4,292
Conn Res Cms[n]	Water Permeation through Monolayers of Zwitterionic Amphiphiles	6/67-12/69	$15,316
UConn Res Fnd[n]	Electrolyte and Water Permeation through Bimolecular Lipid Membranes	7/71-6/73	$8,750
UConn Res Fnd[n]	Analog Computer model EAI-380	4/71	$13,980
UConn Res Fnd[n]	Effect of Phase Equilibria on Percutaneous Drug Absorption	6/71-6/72	$5,200
National Sci Fnd[n]	Undergraduate Research Summer Program	6/68-9/68	$5,000
UConn Res Fnd[n]	Micellar Properties of N-Alkyl Betaines	6/67-6/68	$5,829
Warner-Lambert Res Institute, NJ	Modification of Drug Action by Solubilization	6/67-6/69	$10,000
Sterling-Winthrop Res Institute, NY	General Support of Research Activities	5/69-5/72	$30,000
Bureau of Health Manpower, NIH	An Integrated Undergraduate Curriculum for Training Pharmacy Students	5/72-5/75	$700,000
BRSG (NIH)	Biomedical Research Support Grant preparer and Program Director	4/79-3/80	$27,000
FMC Corporation Princeton, NJ	General Support of Research Activities	7/79-6/82	$15,000
BRSG (NIH)	Biomedical Research Support Grant preparer and Program Director	4/80-3/81	$25,000
Fisons PLC, UK	Distribution of Cromolyn in the Rabbit Eye	9/80-8/81	$5,500
WHO, Geneva	Intramuscular Sustained Release Formulations of Dapsone	9/80-5/83	$60,888
Fisons PLC, UK	In Vitro Permeation Properties of Selected Chromones	5/80-6/83	$79,375
BRSG (NIH)	Biomedical Research Support Grant	4/81-3/82	$22,000
Cystic Fibrosis Fnd[n] Rockville, MD	Sustained Delivery of Amiloride to the Lung	7/84-6/86	$49,938
NICHD (NIH) and Family Hlth Int, RTP	D-Propranolol as a Vaginal Spermicide	10/85-9/89	$116,649
BRSG (NIH)	Biomedical Research Support Grant preparer and Program Director	4/86-3/87	$18,548
Fisons PLC, UK	Studies on Opticrom Viscous Eye Drops	10/86-2/87	$3,000
BRSG (NIH)	Biomedical Research Support Grant	4/87-3/88	$15,164

RESEARCH PROPOSALS FUNDED (continued):

BRSG (NIH)	Small Instrumentation Program Grant preparer and Program Director	8/87-7/88	$5,000
Sandoz Research Institute, NJ	Development of a Skin Slab Model for Percutaneous Drug Absorption	3/88-6/91	$76,809
Glaxo Inc and Burroughs Wellcome	Carri-Med Controlled Stress Rheometer and the Viscoelasticity of Mucus	12/88	$33,600
BRSG (NIH)	Biomedical Research Support Grant preparer and Program Director	4/90-3/91	$6,375
BRSG (NIH)	Biomedical Research Support Grant preparer and Program Director	4/91-3/92	$5,000
BRSG (NIH)	Small Instrumentation Program Grant preparer and Program Director	8/91-7/92	$5,000
US Dept of Education	Patricia Roberts Harris Graduate Study Fellowship Program (Pharm. Sciences)	8/92-7/95	$30,000
BRSG (NIH)	Small Instrumentation Program Grant preparer and Program Director	7/92-6/93	$5,000
BRSG (NIH)	Small Instrumentation Program Grant preparer and Program Director	7/93-6/94	$13,677

RESEARCH PROPOSALS APPROVED, BUT NOT FUNDED:

US Army Med Res & Dev Cmnd	Percutaneous Absorption of Mustard and Other Substituted Ethylsulfides	6/83-6/86	$300,603
NC Board of Sci & Technology	Percutaneous Absorption of Nicotine and its Role in Green Tobacco Sickness in NC	7/83-12/84	$9,950

GRADUATE STUDENTS SUPERVISED:

Name	University	Degree	Year Awarded	Major/Associate Advisor
WJ McClintock	Purdue	MS	1965	Associate
AY Gore	Purdue	MS	1965	Associate
DR Powell	Purdue	MS	1965	Associate
D Fonner Jr	Purdue	MS	1965	Associate
HF Khorakiwala	Purdue	MS	1965	Associate
JW Parker	Purdue	MS	1965	Associate
GJ Baley	Purdue	MS	1966	Associate
JW Munden	Purdue	MS	1967	Major
J Daruwala	Connecticut	PhD	1968	Major
DW Blois	Connecticut	PhD	1970	Major
MA Augustine	Connecticut	PhD	1970	Major
KA Herzog	Connecticut	PhD	1970	Major
AH Amann	Connecticut	PhD	1971	Major
WH Johns	Connecticut	PhD	1971	Associate
JW Munden	Connecticut	PhD	1972	Major
AA Belmonte	Connecticut	PhD	1972	Major
AR Giaquinto	Connecticut	PhD	1972	Associate

GRADUATE STUDENTS SUPERVISED (continued):

RG Stoll	Connecticut	PhD	1973	Major
SA Gordziel	Connecticut	PhD	1976	Major
MS Roberts	Sydney	PhD	1976	Associate
H Nichol	Sydney	PhD	1976	Associate
TT Yang	USC	PhD	1984	Major
TM Chang	UNC	MS	1984	Major
R Henry	UNC	MS	1985	Associate
JR Siverly	USC	PhD	1986	Major
D Oakley	UNC	PhD	1986	Major
A Jamaludin	USC	PhD	1987	Major
MP Carver	NCSU	PhD	1987	Associate
MB Dorr	UNC	PhD	1988	Associate
JL Wolley	UNC	PhD	1988	Associate
O Pruksananonda	UNC	PhD	1989	Major
T Horton	UNC	MS	1989	Associate
J Jozwiakowski	UNC	MS	1990	Major
S Ruddy	UNC	PhD	1992	Associate
J. Pitts	UNC	PhD	1993	Major
T Horton	UNC	PhD	1993	Associate
K Phares	UNC	PhD	1993	Major

POSTDOCTORAL FELLOWS TRAINED

Postdoctoral Fellow	Title of Project	Source of Support	Dates
Dr. Geoffrey Lee	Drug Permeation through Skin	Fisons PLC	7/80-6/83
Dr. Sompol Prakongpan	Formulation of Dapsone	WHO	12/80-11/81
Dr. Keiko Suzuki	Formulation of Dapsone	WHO	9/82-6/84
" " "	Pulmonary Delivery of Amiloride	Cystic Fib Fnd	7/84-6/85
Dr. Lydia Kaus	D-Propranolol as a Spermicide	NICHD/FHI	10/85-5/87
Dr. Diane Burgess	Microspheres in Drug Delivery	Cystic Fib Fnd	12/85-6/86

BIBLIOGRAPHY

PEER REVIEW JOURNALS:

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- Swarbrick J and Carless JE. Phase Equilibria in Some Betaine-Benzaldehyde-Water Systems. *J Pharm Pharmacol,* 15:507-517, 1963
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- Carless JE and Swarbrick J. The Solubility of Benzaldehyde in Water as Determined by Refractive Index Measurements. *J Pharm Pharmacol,* 16:670-676, 1964
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- Swarbrick J. Solubilized Systems in Pharmacy. *J Pharm Sci,* 54:1229-1237, 1965
- McClintock WJ, Swarbrick J, Christian JE and Banker GS. Nuclear In Vitro Method of Continuously Measuring Dissolution Rates. *J Pharm Sci,* 54:1782-1786, 1965
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- Fonner, DE, Banker GS and Swarbrick J. Micromeritics of Granular Pharmaceutical Solids, II. *J Pharm Sci,* 55:576-580, 1966
- Powell DR, Swarbrick J and Banker GS. Effects of Shear Processing and Thermal Exposure on the Viscosity-Stability of Polymer Solutions. *J Pharm Sci,* 55:601-605, 1966
- Banker GS, Gore AY and Swarbrick J. Water Vapour Transmission Properties of Free Polymer Films. *J Pharm Pharmacol,* 18:457-466, 1966
- Banker GS, Gore AY and Swarbrick J. Water Vapour Transmission Properties of Applied Polymer Films. *J Pharm Pharmacol,* 18:205S-211S, 1966
- Swarbrick J. Phase Equilibrium Diagrams: An Approach to the Formulation of Solubilized and Emulsified Systems. *J Soc Cosmetic Chemists,* 19:187-209, 1968
- Swarbrick J and Amann AH. Moisture Permeation through Polymer Films. *J Pharm Pharmacol,* 20:886-888, 1968
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- Bectel MQ and Swarbrick J. The PMA Foundation: A New Program for Pharmaceutics. *Pharm Tech,* 10(10)56-60, 1986
- Nonionic Surfactants, Vol 1, Marcel Dekker Inc. Reviewed in *J Pharm Sci,* 56: 663, 1967
- Cationic Surfactants, Vol 2, Marcel Dekker Inc. Reviewed in *J Pharm Sci,* 59: 1365, 1970
- Introduction to Biopharmaceutics, Lea & Febiger. Reviewed in *J Pharm Sci.* 61: 654, 1972
- Advances in the Pharmaceutical Sciences, Vol 4, Academic Press. Reviewed in *Aust J Pharm Sci,* NS5: 96, 1975
- Clinical Pharmacy Sourcebook. Reviewed in *Modern Medicine,* 1976
- Principles and Perspectives in Drug Bioavailability, Karger. Reviewed in *Pharmaceutical Technology,* 3(6): 165, 197- Controlling the Use of Therapeutic Drugs, American Enterprise Institute. Reviewed in *Pharmaceutical Technology,* 4(1): 96, 1980
- Biopharmaceutics and Drug Interactions, Raven Press. Reviewed in *Pharmaceutical Technology,* 8(2): 69, 1984
-.Clarke's Isolation and Identification of Drugs, Pharmaceutical Press. Reviewed in *J. Pharm Sci,* 76:420, 1987

INVITED SPEAKER, SEMINARS PRESENTED:

- Abbott Laboratories, Chicago. *Phase Equilibrium Diagrams: A Systemic Approach to the Formulation of Solubilized and Emulsified Systems,* April 1965
- Purdue University, Professional Pharmacy Clinic. *National Health Services in Britain,* April 1965
- Pfizer Laboratories, Brooklyn, NY. *Formulation of Coarse Dispersions,* June 1966
- Society of Cosmetic Chemists, Annual Meeting, New York. *Phase Equilibrium Diagrams,* May 1967
- Sterling-Winthrop Research Institute, Rensselaer, NY. *Particle Size Control in Pharmaceutical Dosage Forms,* October 1967
- Albany College of Pharmacy, Albany, NY. *Bioavailability of Oral Dosage Forms,* May 1968
- Merck Sharp & Dohme Laboratories, West Point, PA. *Factors Influencing Drug Permeation Across Biological Membranes,* September 1968
- Warner-Lambert Research Institute, Morris Plains, NJ. *Design and Evaluation of a Three Phase Model System for Drug Transport,* October 1968
- University of Connecticut, Continuing Education Program. *Basic Concepts of Biopharmaceutics,* October 1968

New Hampshire Pharmaceutical Association, Concord, NH. *Biopharmaceutics of Oral Contraceptives,* June 1969

- Ciba Laboratories, Summit, NJ. *Drug Stability in Heterogeneous Dispersions,* September 1969
- Columbia University College of Pharmaceutical Sciences, New York, NY. *In Vitro Models of Dissolution Testing,* May 1970
- Merck Sharp & Dohme Laboratories, Hoddesdon, UK. *The Status of Dissolution Testing in the USA,* July 1970
- Ciba Laboratories, Summit, NJ. *Dissolution Testing,* September 1970
- Sterling-Winthrop Research Institute, Rensselaer, NY. *Increasing the Absorption of Selected Drugs,* November 1970

INVITED SPEAKER, SEMINARS PRESENTED (continued):

- Astra Pharmaceutical Company, Sodertalje, Sweden. *Series of five lectures on Drug Dissolution and Absorption,* July-August 1971
- Swedish Institute for Surface Chemistry, Stockholm. *Use of the Film Balance to Study Molecular Interactions at Interfaces,* August 1971
- Swedish Pharmaceutical Society, Stockholm. *Drug Transport and Dissolution,* September 1971
- University of Florida, Gainesville, FL. *Interfacial Studies of Alkylbenzyldimethyl ammonium Halides,* April 1972
- Smith Kline & French Laboratories, Philadelphia, PA. *Ways to Enhance Oral Bioavailability,* May 1972
- Albany County Pharmaceutical Association, Albany, NY. *Microencapsulation of Drugs,* April 1973
- 11th Annual Midwest Regional Meeting, IPT Section, Chicago. *In Vitro Dissolution Testing,* October, 1973
- Swedish Academy of Pharmaceutical Sciences, Stockholm. *Dissolution Testing as an Indicator of Bioavailability,* October 1974
- Arden House 10th Education Conference (Faculty member), Harriman, NY. *Bioavailability and Formulation,* January 1975
- IPT Symposium, APhA Meeting, San Francisco, CA. *Dissolution Testing: Today and Tomorrow,* April 1975
- University of Sydney Workshop, Leura, NSW. *Factors Affecting Absorption of Drugs: In Vitro and In Vivo Model Studies,* August 1975
- Royal Australian Chemical Institute, Syndey, NSW. *Recent Advances in Drug Development,* September 1975
- Victorian College of Pharmacy, Melbourne, Vic. *A New Curriculum for Pharmacy,* September 1975
- Australian Society of Cosmetic Chemists, Sydney, NSW. *Formulation of Solubilized and Emulsified Systems,* November 1975
- Society of Hospital Pharmacists of Australia, Sydney, NSW. *Pharmacy Education in the USA,* November 1975
- Association of Health Professions of Australia, Sydney, NSW. *Compulsory Continuing Professional Education,* November 1975
- Royal Australian Chemical Institute, Melbourne, Vic. *New Methods of Drug Delivery,* February 1976
- 29th Congress of the Pharmaceutical Association of Australia and New Zealand, Adelaide, SA. *The Role of the Pharmaceutical Educator in Continuing Professional Education,* April 1976
- 47th Australian and New Zealand Association for the Advancement of Science, Hobart, Tas. *Drug Delivery Systems of the Future,* May 1976
- Pharmaceutical Society of Queensland, Brisbane. *Professional and Continuing Education of the Pharmacist,* May 1976
- Australian Society of Cosmetic Chemists, Sydney, NSW. *Formulation of Controlled Release Preparations,* July 1976
- ICI Americas, Wilmington, Del. *Novel Approaches to Drug Delivery,* August 1976
- International House, London University. *The Role of the Pharmacist in Health Care,* January 1977
- Guild of Hospital Pharmacists, London. *Pre-registration Experience for Pharmacists,* February 1977
- University of Southern California, Los Angeles, CA. *Some Interfacial Phenomena of Pharmaceutical and Biological Significance,* March 1977
- FMC Corporation Meeting, Marbella, Spain. *Rational Formulation of Solid Dosage Forms,* May 1977

INVITED SPEAKER, SEMINARS PRESENTED (continued):

- Federation International Pharmaceutique (FIP) Congress, The Hague, The Netherlands, Colloquium on *Professional and Legal Aspects of Drug Selection,* September 1977
- Xth Central American Congress of Pharmaceutical Sciences, San Jose, Costa Rica, *Pharmaceutical Education - Which Way To Go?* October 1977
- University of Panama, Panama City. *Series of four lectures on In Vivo-In Vitro Correlations in Drug Testing,* January 1978
- College of Pharmaceutical Sciences of Panama, Panama City. *New Directions in Pharmacy Education,* January 1978
- Pharmaceutical Society of Great Britain, Epsom Branch. *Relevance of Pharmacy Education in Practice,* March 1978
- Malaysian Pharmaceutical Society, Kuala Lumpur, Malaysia. *Educational Trends in Pharmacy,* March 1978
- Science University of Malaysia, Penang, Malaysia. *Permeation of Phenolic Compounds Through Human Skin,* April 1978
- Association of Teaching Hospital Pharmacists, London. *Trends in Pharmaceutical Education,* May 1978
- American Critical Care Laboratories, Chicago. *Drug Permeation through Human Skin,* June 1978
- New England Respiratory Conference, Hyannis, Mass. *Modern Drug Delivery Systems for Pulmonary Diseases,* July 1978
- Pan American Health Organization Seminar, Panama City, Panama. *The Need for Drug Product Quality Control in Central America,* January 1979
- 1st FMC Seminar West, Los Angeles, CA. *Dissolution Testing - Can We Expect A Solution?* January 1979
- University of Southern California, Los Angeles, CA. *Percutaneous Absorption of Phenolic Compounds,* March 1979
- FMC Industrial Seminar, Montreal and Toronto, Canada. *Dissolution Testing in Product Development,* October 1979
- University of Southern California Continuing Education Program, Alaska Cruise. *Bioavailability and Product Selection by Pharmacists,* July 1979
- Santa Monica Bay Area Pharmaceutical Association, Los Angeles, CA. *Permeation of Drugs Through Human Skin,* August 1979
- ICI Americas, Wilmington, Del. *Percutaneous Absorption as a Method of Drug Delivery,* August 1979
- Syntex Laboratories, Mexico City, Mexico. *The Role of Dissolution Testing in Product Optimization,* October 1979
- Mexican Pharmaceutical Association Meeting, Guanajuarto, Mexico. *Bioavailability Studies in Drug Development,* October 1979
- Fisons Pharmaceuticals Ltd., England. *Optimizing the Formulation of Ophthalmic Products,* March 1980
- World Health Organization, Geneva, Switzerland. *Prolonged Release Technologies as Might Be Applied to Dapsone,* THELEP Drug Development Meeting, April 1980
- Fisons Pharmaceuticals Ltd., England. *Prolonging the Action of Orally Administered Drugs,* January 1981
- El Fateh University, Tripoli, Libya. *Bioavailability as a Factor in Quality Control,* March 1981
- IPT Symposium, APhA Meeting, St. Louis, MO. *Organization Within the Pharmaceutical Industry,* April 1981
- Centenary Symposium on Pharmacy Practice, New Zealand Pharmaceutical Society, Auckland, NZ. Plenary lecture on *The Next 100 Years of Pharmacy Practice*, July 1981
- Department of Pharmacy, Central Institute of Technology, Wellington, New Zealand. *Drug Permeation Studies Using Human Skin,* July 1981
- Department of Pharmacy, University of Otago, Dunedin, New Zealand. *Development of Sustained Release Intramuscular Injections,* July 1981

INVITED SPEAKER, SEMINARS PRESENTED (continued):

- Burroughs Wellcome Co., Greenville, NC. *Surface Reaction Approach to the Formulation of Sustained Release Forms of Dapsone,* February 1982
- National University of Singapore. *Development of Intramuscular Sustained Release Injection in Leprosy,* March 1982
- Pharmaceutical Society of Singapore. *New Approaches to Drug Delivery,* April 1982
- Faculty of Pharmacy, Mahidol University, Bangkok, Thailand. *Permeation of Drugs Through Human Skin,* April 1982
- Burroughs Wellcome Co., Greenville, NC. *Percutaneous Absorption in Man,* December 1982
- Fisons plc, Pharmaceutical Division, Loughborough, England. *Effect of Lipophilic Vehicle on the Disposition of Sodium Cromoglycate in the Rabbit Eye,* April 1983
- Fisons plc, Pharmaceutical Division, Loughborough, England. *Studies on the Percutaneous Absorption of Chromone-2-carboxylic Acids and Esters,* July 1983
- Society of Cosmetic Chemists, Carolina Chapter, Raleigh NC. *Factors Affecting Percutaneous Absorption,* September 1984
- Fisons plc, Pharmaceutical Division, Loughborough, England. *Fluidization and Dosage Form Design and Performance,* February 1985
- Course on *Principles of Emulsion and Suspension Technology,* UNC School of Pharmacy, February 1985. Course Director and Lecturer
- Astra Pharmaceutical Company, Sodertalje, Sweden. *Novel Approaches to Sustained Release and Factors Influencing Transport of Drugs through Skin,* April 1985
- Sterling-Winthrop Research Center, Alnwick, England. *Percutaneous Absorption of Ionizable Compounds,* May 1985
- Family Health International, Expert meeting on *Development of Spermicides*, Raleigh, NC. *Formulation Approaches,* December 1985.
- Greater Raleigh Pharmaceutical Discussion Group, Zebulon, NC. *Bridging the Gap between Product Development and Production,* February 1986
- Pharmaceutical Manufacturers Association (Production, Engineering, and Materials Management Section), *Production Symposium*, Raleigh, NC. April 1986
- PharmTech Conference, Cherry Hill, NJ. Session Chairman for *Contracting Outside Services and Skills,* September 1986
- Pharmacy Practice Seminar Series, UNC, Chapel Hill. *The Role of Basic Science in the Pharmacy Curriculum,* March 1987
- Family Health International, Research Triangle Park, N.C. *Formulation Development of Vaginal Delivery Systems,* July 1987
- Pharm. Tech. Conference, The Meadowlands, N.J. Session Chairman for *Effervescence: The Underutilized Technology,* September 1987
- North Carolina Pharmaceutical Discussion Group, Wilson, N.C. *Transdermal Drug Delivery,* November 1987
- Interpharm Conference, U.K. *Industry-University Collaborations in the USA,* May 1988
- South African Congress of Pharmaceutical Sciences, (plenary lecture) *Transdermal Drug Delivery*; Port Elizabeth, South Africa *The Funding of Research in the Pharmaceutical Sciences* (Banquet speech), May 1988
- University of the Western Cape, Cape Town, South Africa *Controlled Drug Release,* May 1988
- Radio South Africa *Drug Delivery to the Lung and Vagina,* May 1988
- School of Pharmacy, Rhodes University, Grahamstown, South Africa *Effect of Drugs on Mucus"* May 1988
- Department of Pharmacy, University of Pretoria, Pretoria, South Africa *Viscoelasticity of Mucus,* June 1988
- Medical University of Southern Africa, Medunsa, South Africa *Effect of Drugs on Viscoelasticity of Mucus,* June 1988

INVITED SPEAKER, SEMINARS PRESENTED (continued):

- Department of Pharmacy, Potchefstroom University, Potchefstroom, South Africa *Physicochemical Properties of Mucus,* June 1988
- Brighton Polytechnic, U.K., *Hydration and Dehydration of Mucus,* July 1988
- College of Pharmacy Practice, London, U.K., *American Pharmacy Undergraduate Courses and Their Products,* July 1988
- PharmTech Conference, Philadelphia, PA, *Scientific Manuscript Writing and Organization or How to Make It To The Best Seller List!,* September 1989
- North Carolina Pharmaceutical Discussion Group, Chapel Hill, NC, *The Promise and Potential of Biotechnology,* October 1989
- PharmTech Conference, New Brunswick, NJ, *Bridging the Interface between Product Development and Production,* September 1990
- Shanghai Medical University, People's Republic of China, Two lectures on *Controlled Drug Release* and *Effect of Mucus on Drug Delivery,* April 1991
- Shanghai Pharmaceutical Society, Shanghai, People's Republic of China, *Transdermal Drug Delivery,* April 1991
- Shanghai Institute of Pharmaceutical Technology, Shanghai, People's Republic of China, *Formulation of Modern Pharmaceutical Products,* April 1991
- Faculty of Pharmacy, National University, Mexico City, Mexico. *Non-Device Approaches to Controlled Release,* June 1991
- Instituto Tecnologico de Estudios Superiores de Monterrey, Mexico City, Mexico. 12 hour lecture course on *Aspects of Controlled Drug Release* for Diplomado en Tecnologia Farmaceutica, June 1991
- First International Symposium on Applied Chemistry, Instituto Tecnologico de Estudios Superiores de Monterrey, Monterrey, Mexico. *Physico-Chemical Factors Affecting Drug Activity,* October, 1991
- School of Pharmacy, University of Wisconsin - Madison. *Teaching, Research and Service in a Professional Program within a Research University,* November, 1991.
- AAPS 5th Annual Meeting, Washington, D.C.,*Computer Assisted Drug Design and Selection*, PDD/MNPC Joint Symposium, November 1991.
- School of Pharmacy, University of North Carolina at Chapel Hill. *The Pursuit of Excellence and Balance in Teaching, Research and Service at a Professional School in a Research-Intensive University,* December 1991.
- Arden House Conference, Harriman, NY. *Do Processing and Scale-Up Factors Really Affect Bioavailability?*, January 1992
- Pharm Tech '92 Conference, East Brunswick, NJ. *Pharmaceutical Aerosols and Inhalation Products,* September 1992.
- AAI Annual Development Seminar, Wilmington, NC. *Good Development Practices -- A Concept Whose Time Has Come?,* June 1993.
- Fourteenth Annual Congress of the South African Academy of Pharmaceutical Sciences, Durban, South Africa. Plenary Lecture on *Drug Distribution in the Skin: An In Vitro-In Vivo Comparison using Estradiol as a Model Compound,* June 1993.
- 34th Symposium of Associazione Farmaceutica Industria (AFI), Venice, Italy. *Advances in Controlled Drug Delivery,* May, 1994.
- PharmTech '95 Conference, East Brunswick, NJ. *Problems Associated with the Use of Bulk Drug Chemicals,* September, 1995.
- Nova Nordisk, Copenhagen, Denmark. *Good Formulation Development Practices*, November 1995.
- Associazione Farmaceutica Industria (AFI) Seminar, Milan, Italy. *Good Formulation Development Practices*, November 1995.
- Tablet Manufacturing Conference, Techsource, Atlantic City, NJ. *Preparation of Low Dose Oral Solid Dosage Forms*, May 1996.

INVITED SPEAKER, SEMINARS PRESENTED (continued):

- Twenty Fifth InterPharm Research Conference, Weston on the Green, UK. *Outsourcing – An American View,* May 1997.
- Fourth Annual PharmTech Conference Puerto Rico, Rio Grande, PR. *Change-Induced Problems in Tablet Manufacture – and Supac-IR*, June 1997.
- Twenty Sixth InterPharm Research Conference, Usk, South Wales, UK. *Enhanced Absorption using ProSorb Technology,* May 1998.
- Compliance and Validation Issues "98", Techsource, Atlantic City, NJ. *SUPAC Guidelines -- Important Keys to Compliance*, June 1998.
- PhRMA Foundation Annual Awardee Meeting, New York, NY. *The Role of Rapidly Absorbed Non-Steroidal Anti-Inflammatory Agents in the Abortive Treatment of Migraine*, April, 1999.
- Twenty Seventh InterPharm Research Conference, Usk, South Wales, UK. *SUPAC -- From Concept to Formulation Tool,* May 1999.
- International Business Communications' (IBC's) 3rd Annual Conference on Migraine -- Novel Drug and Therapeutic Development, Philadelphia, PA. *ProSorb™ Technology Creates Rapid Absorption of NSAIDs Used in the Treatment of Migraine,* May 1999.
- AAPS Southeast Regional Meeting, Durham, NC. Plenary Lecture on *The Role of Contract Research and Product Development Organizations in the Drug Development Process*, June 1999.